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Dated: May 31, 2011
Electronic Signature for: Brian C. Trinque, Ph.D. / Brian C. Trinque, Ph.D./

Docket No.: 514226
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Kenichi Chiba *et al.*

Application No.: 10/657,910

Confirmation No.: 5169

Filed: September, 9, 2003

Art Unit: 1625

For: MACROCYCLIC COMPOUNDS USEFUL AS
PHARMACEUTICALS

Examiner: T. Oh

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR § 1.705(b)(2)

Dear Sir or Madam:

1. This statement is respectfully submitted in support of the “Request for Reconsideration of Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(d)” for the above-referenced application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of 490 days.
2. The patent term adjustment as shown on the face of the Issue Notification, mailed on March 9, 2011 is 525 days. A copy of the Office’s Patent Term Adjustment calculation (“PTA Sheet”), available on PAIR, is also submitted herewith as Appendix A. Applicants respectfully submit that the determination of 525 days of patent term adjustment is incorrect for the reasons discussed below.

3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay).

As set forth in the Application for Patent Term Adjustment under 37 CFR §1.705(b), filed by Patentees on January 19, 2011, the total period of delay corresponding to the sum of “14 Month Delay” pursuant to §1.703(a)(1) (78 days) and “Four Month Delay” pursuant to §1.703(a)(2) (105 days) is 183 days (see page 2 of the January 19, 2011 Application). Patentees note that this period of delay is accurately reflected on the PAIR PTA Sheet of Appendix A.

Also set forth in the Application of January 19, 2011 was Patentees’ calculation of “Three Years Delay” pursuant to 37 CFR §1.703(b) (970 days), *which was based on a projected issue date of May 3, 2011*. Patentees note that this number is currently reflected on the PAIR PTA Sheet of Appendix A. Patentees believe that this number is inaccurate, however, because the instant patent issued on March 29, 2011, rather than May 3, 2011, corresponding to a difference of 35 days. Accordingly, the correct “Three Years Delay” pursuant to 37 CFR §1.703(b) is 935 days.

In accordance with 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of 14 Month Delay (78 days, ending January 26, 2005), and the period of 4 Month Delay (105 days, ending March 16, 2006), and the period of Three Years Delay (935 days, beginning on September 10, 2006 and ending on March 29, 2011). These periods of delay do not overlap. Accordingly, the total examination delay is 1118 days.

B. “Applicant Delay” Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704, the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. Patentees note the Office’s calculation of Applicant Delay equal to 628 days.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)

As set forth in 37 CFR §1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of Examination Delays reduced by the period of Applicant Delay (*i.e.*, 1118 days – 628 days = 490 days). Therefore, Applicants submit that the correct patent term adjustment for the above-referenced application is 490 days.

In accordance with 37 CFR §1.705(b)(2)(iii), Applicants submit that the present application is subject to a terminal disclaimer over U.S. Patent No. 7,799,827.

Dated: May 31, 2011

Respectfully submitted,

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